Consent in Medical Practice 1

– *Understanding the Concepts behind the Practice*

By Dr T Thirumoorthy, Executive Director, SMA Centre for Medical Ethics & Professionalism

This is the first instalment of a series on informed consent, which is a very wide topic. In this article, the basic underlying concepts in medical consent are explained. These concepts are a basis to finding solutions to several ethical and legal dilemmas arising from consent taking processes in medical practice.

Introduction

In medical practice, it is not unusual for doctors to stick needles and draw blood, insert instruments into human body orifices, and even amputate a human being's entire limb.

All this would be considered illegal, *battery* and even bordering on *homicide* (if death occurs), except for three factors: firstly, it is done by a registered medical practitioner; secondly, equally important is that the patient has consented to the procedure; and thirdly, it is carried out in a therapeutic relationship within a healthcare setting. Therefore, consent is not an option but a necessity in medical practice.

The legal and ethical basis

Consent is not only necessary to prevent *legal action for assault or battery*, but also essential to defend any suit in medical negligence. A doctor has a legal duty to advise and inform in the care of her patient. For valid consent, the patient must be informed in "broad terms" of the nature and purpose of the medical procedure. Valid consent provides a defence to the tort of battery.

Consent has its basis in medical ethics by subscribing to **the principle of respect for patient autonomy**. Patient autonomy in clinical Medicine is the right of every person to determine what is done to him medically and to be actively involved in medical decision making.

The principle of beneficence in medical ethics is fundamentally based on the concern for the patient's welfare. It is practically impossible to provide beneficent medical care to our patients if we, as clinicians, do not spend time understanding their wishes, expectations, concerns and values, and getting their consent.

Consent in medical practice displays respect for the wishes, and concern for the welfare of the patient. Respect for the patient's wishes and welfare is the premise for **the principle of respect for persons**. Consent finds its basis in the principle of respect for persons, which is an essential component in building trust in the medical profession and the healthcare system.

The question of when consent is necessary is then raised. Everything in *the doctor-patient relationship is consensual*. Before a clinician examines, treats or cares for a competent adult, she must obtain the patient's consent. It is an active communicative process, an educational activity and a process of building trust and mutual respect.

The elements of informed consent

- Capacity: all adult patients are assumed to have capacity to consent (competent), unless certified otherwise.
- Disclosure: patients need to be sufficiently and appropriately informed, to understand the information provided before they can give consent. The amount of information provided should take consideration of the patients' wishes, the nature and complexity of the procedures, the benefits, and the seriousness and likelihood of the risks or complications.
- Voluntariness: consent must be given freely and void of any form of coercion, duress or undue influence by family, friends, employers, insurers and healthcare professionals.

The consent form

Consent in Medicine is not just an act of filling up a consent form. A signed and accurate consent form is an important and valid documentation of the consent process. Properly filling in consent forms and documenting the consent process accurately, clearly and comprehensively form an important defence against any future legal action in clinical negligence or battery. Good documentation of the consent process cannot be overemphasised. The consent form also serves as a means of documentation and communication for the other members of the healthcare team about the treatment plan for the patient.

Explicit (formal) or written consent

Explicit (formal) or written consent using consent forms is expected in:

- Surgical and invasive therapeutic procedures;
- Chemotherapy and radiotherapy;
- Administering or prescribing drugs with special risks, like teratogenicity;
- Invasive radiological and investigational procedures;
- Medical research;
- Teaching activities, especially those involving intimate examinations; and
- Medical reports and sharing of patients' medical information where there is risk of breaching confidentiality inappropriately.

If there are any material risks (the risk of importance to the patient or the risk of delay), they must be spelt out in the documentation.

Implied consent

Not all consent has to be written or documented fully. In much of clinical practice, where the patient is seeking medical help to relieve his suffering or pain, consent is implied consent. Implied consent is measured by the actions of the patient: stretching out his hand for blood taking, or taking off clothes and lying on the couch when requested for a clinical examination. Implied consent is not implied or informed compliance. In implied consent, the patient must be informed what is to be done and be given an opportunity to refuse.

In many other clinical situations where implied consent is exercised, consent could be recorded in the clinical notes under plan of action, for example: "Discussed options with patient, he preferred delaying surgery for a trial of conservative medical treatment. Risk and benefits explained and understood. Condition to be reviewed in one week."

> ***"Consent is not an option but a necessity in medical practice.***

Tacit consent

Tacit consent is often used to describe the opt-out system, or by an act of omission and silently not objecting. Here a patient or person not agreeing for a procedure has to take active action to refuse, if he does not want the procedure done on him. For example, some hospitals practice opt-out consent for HIV testing, while some countries have moved to an opt-out system to donation of organs at death. However, tacit consent, like all consent processes, must fulfil three basic features, namely:

1. Capacity: understand the information, retain and consider (weigh the choices) and make a decision.
2. Disclosure: adequate information must be given to make the decision.
3. Voluntariness: must be done out of free will and under no coercion.

Anticipatory consent

Anticipatory consent is the consent taken where additional problems or situations may arise and the patient may not be able to consent as she may temporarily lack the capacity. This is not uncommon in surgery, when the surgeon has to perform an important or crucial surgical manoeuvre based on operative findings intraoperatively and the patient is not able to consent as he is under anaesthesia. Therefore, it is important to obtain anticipatory consent by discussing

Photo: iStockphoto

> ***"Everything in the doctor-patient relationship is consensual.***

with the patient all foreseeable situations and what kind of actions may need to be taken, before major surgery. To proceed without consent may not be defensible in clinical negligence, unless it is lifesaving (the principle of necessity). In discussing anticipatory consent, the patient may agree or consent through conditional consent. Conditional consent describes consent of limited scope or with conditions: like lumpectomy and not mastectomy, or like myomectomy and not hysterectomy.

Delay or refusal of beneficial treatment

It must be recognised that consent and *refusal of treatment* in Medicine are two sides of the same coin. The legal principle in consent gives the mentally competent adult patient the right to refuse medical treatment for any reason, even when the decision may lead to his own harm.

Therefore, it is equally important to record the consent clearly, even in the delay or refusal of surgery, therapy or investigations as part of the consent process. Medical records are essential when any defence against negligence in consent arise in future – otherwise, *"If only I was told of the risk by the doctor, I would not have delayed the surgery and thus avoided the complications I am now in"* would be the plaintiff's claim in court.

Patients may change their minds and *withdraw consent* anytime. Once consent is withdrawn, the procedure cannot proceed. Informed consent is based on the patient's values, preferences, beliefs, expectations and concerns. However, his expectations and concerns are not always based on facts, reason and logic.

Disclosure in informed consent

Information to disclose to the patient include:

- Procedure: the nature of the procedure, including the indications;
- Benefits and consequences of the procedure;
- Risks associated with the procedure;
- Alternatives (including doing nothing), their benefits, risks and consequences; and
- Questions asked by the patient and explanations provided.

All questions asked by the patient, including the uncertainties involved in the procedure, should be answered openly and honestly. (The mnemonic used to remember the abovementioned points is PBRAQ.)

Consent cannot be presumed on medical facts

Consent cannot be presumed from the doctor's point of view or based only on medical indications. It is not defensible to say: *"I did a hysterectomy as the condition of the uterus was such that it would be dangerous and even life-threatening for the patient to become pregnant. Moreover, she has already five healthy children."*

Medical paternalism is where the doctor makes the decision based on the medical facts and what she believes is best for the competent patient without the latter's input and participation, which conflicts significantly with the principles of respect for person and patient autonomy. In such a situation, respect for patient autonomy would take precedence, both on legal and ethical grounds. A doctor may have difficulty in predicting accurately the patient's preferences, thus it is necessary to involve the patient in decision making and get consent.

Consent in emergencies

The principle of necessity states that acting out of necessity legitimates a wrongful act in criminal and civil law. Acting unlawfully is justified if the resulting good effect outweighs the consequence of strictly adhering to the law. The principle of necessity protects a value of greater weight than that of the wrongful act performed.

The principle of necessity in medical practice allows the doctor to proceed with medical treatment or surgery even in the absence of consent. The important factors necessary to seek defence under the principle of necessity includes:

- Unconscious (temporary or permanent incapacity) patient in an emergency situation;
- Procedures essential for the patient's immediate survival or well-being;
- No known objection to treatment (no advanced directives);
- Unreasonable, unethical or dangerous to postpone the procedure;
- Done out of necessity and not convenience; and
- Concurrence of the medical team. SMA

Dr Thirumoorthy is Executive Director of the SMA Centre for Medical Ethics & Professionalism. In addition to being a practicing dermatologist with an interest in medical Dermatology, he serves as teaching faculty in the Practice Course of Duke-NUS Graduate Medical School.